ISO 23500-4:2019 (E)

Preparation and quality management of fluids for haemodialysis and related therapies — Part 4: Concentrates for haemodialysis and related therapies

Contents

Foreword

Introduction

1 Scope

2 Normative references

3 Terms and definitions

4 Requirements

- 4.1 Concentrates
- 4.1.1 Physical state
- 4.1.1.1 Liquid solute concentrations
- 4.1.1.2 Solute concentrations based on powder
- 4.1.2 Water
- 4.1.3 Bacteriology of concentrates
- 4.1.3.1 Bacteriology of acid concentrates
- 4.1.3.2 Bacteriology of bicarbonate concentrates
- 4.1.4 Endotoxin levels
- 4.1.5 Fill quantity
- 4.1.6 Chemical grade
- 4.1.7 Particulates
- 4.1.8 Additives — “Spikes”
- 4.1.9 Containers
- 4.1.10 Bulk-delivered concentrate
- 4.1.11 Concentrate generators
- 4.2 Manufacturing equipment
- 4.3 Systems for bulk mixing concentrate at a dialysis facility
- 4.3.1 General
- 4.3.2 Materials compatibility
- 4.3.3 Disinfection protection
- 4.3.3.1 General
- 4.3.3.2 System lock out
- 4.3.4 Safety requirements
- 4.3.5 Bulk storage tanks
- 4.3.6 Ultraviolet irradiators
- 4.3.7 Piping systems
- 4.3.8 Electrical safety requirements

5 Tests

- 5.1 General
- 5.2 Concentrates
- 5.2.1 Physical state
- 5.2.2 Solute concentrations
- 5.2.2.1 Liquid solute concentrations
- 5.2.2.2 Solute concentrations from powder
- 5.2.3 Water
- 5.2.4 Microbial contaminant test methods for bicarbonate concentrates
- 5.2.5 Endotoxin levels
- 5.2.6 Fill quantity
- 5.2.7 Chemical grade
- 5.2.8 Particulates

5.2.9 Additives — “Spikes”
5.2.10 Containers
5.2.11 Bulk delivered concentrate
5.2.12 Concentrate generators
5.3 Manufacturing equipment
5.4 Systems for mixing concentrate at a dialysis facility
5.4.1 General
5.4.2 Materials compatibility
5.4.3 Disinfection protection
5.4.3.1 General
5.4.3.2 System lock out
5.4.4 Safety requirements
5.4.5 Bulk storage tanks
5.4.6 Ultraviolet irradiators
5.4.7 Piping systems
5.4.8 Electrical safety requirements

6 Labelling

6.1 General
6.2 General labelling requirements for concentrates
6.3 Labelling requirements for liquid concentrate
6.4 Labelling requirements for powder concentrate
6.5 Additives
6.6 Labelling requirements for concentrate generators
6.7 Labelling for concentrate mixer systems
6.7.1 General
6.7.2 Product literature for concentrate mixers

Annex A (informative) Rationale for the development and provisions of this document

A.1 Scope
A.2 Requirements
A.2.1 General
A.2.1.1 Overview
A.2.1.2 Physical state
A.2.1.3 Solute concentrations
A.2.1.4 Water
A.2.1.5 Microbiology of bicarbonate concentrates
A.2.1.6 Fill quantity
A.2.1.7 Chemical grade
A.2.1.8 Additives — “Spikes”
A.2.1.9 Containers
A.2.1.10 Endotoxin levels
A.2.1.11 Bulk delivery concentrate
A.2.1.12 Concentrate generator systems
A.2.2 Manufacturing equipment
A.2.2.1 General
A.2.2.2 Endotoxin levels
A.3 Labelling
A.3.1 General
A.3.2 Labelling requirements for liquid concentrate
A.3.3 Labelling requirements for powder concentrate

Page count: 22